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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,829	10/20/2004	Motoo Sumida	47233-0045 (219711)	8556
55694 7590 02/20/2009 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209			EXAMINER CUTLIF, YATE KAI RENE	
			ART UNIT 1621	PAPER NUMBER
			MAIL DATE 02/20/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/511,829

Applicant(s)

SUMIDA ET AL.

Examiner

YATE' K. CUTLIFF

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 5, 8-21, 24, 27 - 35 is/are pending in the application.
- 4a) Of the above claim(s) 8-14, 19, 20 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 15-18, 21, 27 & 29-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1, 4, 5, 8 - 21, 24, 27 - 35 are pending.
Claims 2, 3, 6, 7, 22, 23, 25 and 26 have been canceled
Claims 8 -14, 19, 20, and 28 have been withdrawn.
Claims 1, 4, 5, 15 - 18, 21, 24, 27, and 29-35 are rejected.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 16, 2008 has been entered.

Response to Arguments

3. Applicant's arguments, see pages 7, filed December 16, 2008, with respect to the rejection(s) of claim(s) 1, 4, 21, 24 and 26 under 35 U.S.C. 102(b) have been fully considered and are persuasive in view of the amendment to the claims and arguments presented. Therefore, the rejection has been withdrawn.
4. Applicant's arguments, see pages 8-13, filed December 16, 2009, with respect to the rejection(s) of claim(s) 1, 4, 5, 7, 15-18, 21, 24, 27 and 29 - 32 under 35 U.S.C. 103(a) have been fully considered and are persuasive in view of the amendment and arguments. Therefore, the rejection has been withdrawn. However, upon further

consideration, a new ground(s) of rejection is made in view of Williams et al. (Science, 1961, vol. 133) in view of Egger et al. (Phytochemistry, 1967, 6(3)) and further in view of Asami et al. (US 6,265,450) as set out below.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 4, 5, 33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (Science, 1961, vol. 133) in view of Egger et al. (Phytochemistry, 1967, 6(3)).
9. The rejected claims cover, inter alia, a purified astaxanthin medium-chain fatty acid ester, wherein the medium-chain fatty acid ester is a monoester, and wherein the medium-chain fatty acid has 8 to 10 carbon atoms. Further, the medium chain fatty acid can have an even number of carbon atoms or have 8 carbon atoms.
10. Williams et al. discloses that lapides of *Ankistrodesmus braunii* contain astaxanthin and that the fatty acids fractions found contain capric acid and caprylic acid. (see Fig. 1. Also, Williams et al. states that like vegetable oil algal oil would be digestible and nutritious for human beings.
11. Further, Egger, et al. discloses that the fatty acid compounds of the kertocarotenoid esters in the petals of *Adonis annua* (esters of astaxanthin) were found to contain capric acid.
12. The factors to be considered in determining whether a purified form of an old product is obvious over the prior art include whether the claimed chemical compound or composition has the same utility as closely related materials in the prior art, and whether the prior art suggests the particular form or structure of the claimed material or suitable methods of obtaining that form or structure. In re Cofer, 354 F.2d 664, 148 USPQ 268 (CCPA 1966). In this instance the Williams reference uses absorption chromatography to isolate the astaxanthin and fatty acid. Further, it is stated that it has nutritional value which means it can be used in food.

13. Egger et al. is silent with regard to the use of ester, however, one of ordinary skill in considering the disclosure of Williams et al. could reasonably expect that the astaxanthin ester of Egger et al. would have a comparable use.
14. Claims 21, 15-18, 24 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Egger et al. (Phytochemistry, 1967, 6(3)) in view of Asami et al. (US 6,265,450) and further in view of Williams et al. (Science, 1961, vol. 133).
15. Rejected claim 21 covers, inter alia, a composition comprising at least 0.1% of an astaxanthin medium-chain fatty acid ester, wherein the medium-chain fatty acid ester is a monoester, and wherein the medium-chain fatty acid has 8 to 10 carbon atoms. Dependent claims 15-18 disclose uses for the composition as a food composition, food additive, cosmetic, or animal feed. Further, dependent claim 24 discloses that the composition has an even number of carbons.
16. Rejected claim 34 covers a cosmetic comprising astaxanthin medium-chain fatty acid ester, wherein the medium-chain fatty acid ester is a monoester, and wherein the medium-chain fatty acid has 8 to 10 carbon atoms.
17. Egger, et al. discloses that the fatty acid compounds of the kercarotenoid esters in the petals of *A. annua* (esters of astaxanthin) were found to contain capric acid.
18. The difference between the claimed invention and Egger is that it does not disclose the use of the astaxanthin medium-chain fatty acid ester with food, cosmetics and feed.

19. However, Asami et al. discloses that astaxanthin and/or its esters has been found in shrimp eggs, animal organs, plants and chemically synthesized products are easily available. (see column 4, lines 21-37). Further, it is stated that extracts containing astaxanthin and/or its esters that have been purified by any of the processes disclosed in the references, from known sources, can be used as active ingredients in their invention. (see column 6, lines 16-27). Asami et al. uses its astaxanthin esters in compositions in the form of pharmaceutical, functional food, food or beverage. (see abstract). Asami et al. fails to specifically disclose that the astaxanthin mono-ester includes a medium-chain fatty acid with 8 to 10 carbon atoms, but uses long chain fatty acid esters of astaxanthin. However, Asami et al. substantially discloses the claimed astaxanthin medium-chain fatty acid monoester in that it teaches that any monoester of a saturated fatty acid is operable in their anti-stress composition, in view of the fact that Williams et al. states that oils of algal are digestible and have nutritious value.

Applicant is reminded that; "[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." In re Preda, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). In the instant case, from the teachings of the references, is it known that astaxanthin medium-chain fatty acid esters have nutritious value.

Because Egger et al. discloses an astaxanthin medium-chain fatty acid ester and Asami et al. states that an astaxanthin of any of the methods disclosed could be used, it would have been obvious to one skilled in the art to prepare a medium chain

astaxanthin fatty acid ester from the incorporated process involving algae and use it in products suggested by Asami et al.

Therefore, the rejected claims would have been obvious because a simple substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (U.S. 2007).

With regard to the percentage of astaxanthin in the claimed composition, this is considered to be within the purview of the skilled artisan, because generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

20. Claims 27 and 29, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (Science, 1961, vol. 133) in view of Asami et al. (US 6,265,450).
21. The rejected claims cover inter alia, a composition comprising at least 0.1% of an astaxanthin medium-chain fatty acid ester, wherein the medium-chain fatty acid ester is a monoester, and wherein the medium-chain fatty acid has 8 to 10 carbon atoms.
22. Williams et al. discloses that lapides of *Ankistrodesmus braunii* contain astaxanthin and that the fatty acids fractions found contain capric acid and caprylic acid.

(see Fig. 1.) Also, Williams et al. states that like vegetable oil algal oil would be digestible and nutritious for human beings.

23. The difference between the claimed invention and Williams et al. is that it does not disclose the use of the astaxanthin medium-chain fatty acid ester with food, cosmetics and feed.

24. However, Asami et al. discloses that astaxanthin and/or its esters has been found in shrimp eggs, animal organs, plants and chemically synthesized products are easily available. (see column 4, lines 21-37). Further, it is stated that extracts containing astaxanthin and/or its esters that have been purified by any of the processes disclosed in the references, from known sources, can be used as active ingredients in their invention. (see column 6, lines 16-27). Asami et al. uses its astaxanthin esters in compositions in the form of pharmaceutical, functional food, food or beverage. (see abstract). Asami et al. fails to specifically disclose that the astaxanthin mono-ester includes a medium-chain fatty acid with 8 to 10 carbon atoms, but uses long chain fatty acid esters of astaxanthin. However, Asami et al. substantially discloses the claimed astaxanthin medium-chain fatty acid monoester in that it teaches that any monoester of a saturated fatty acid is operable in their anti-stress composition, in view of the fact that Williams et al. states that oils of algal are digestible and have nutritious value.

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instant case, from the teachings of the references, is it known that astaxanthin medium-chain fatty acid esters have nutritious value.

Because Williams et al. discloses an astaxanthin medium-chain fatty acid ester and Asami et al. states that an astaxanthin of any of the methods disclosed, it would have been obvious to one skilled in the art to prepare a medium chain astaxanthin fatty acid ester from the incorporated process involving algae and use it in other products suggested by Asami et al.

Therefore, the rejected claims would have been obvious because a simple substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (U.S. 2007).

With regard to the percentage of astaxanthin in the claimed composition, this is considered to be within the purview of the skilled artisan, because generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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